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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,902	01/09/2006	Roland Schule	033-004	5822
36844 7590 01/15/2008 CERMAK KENEALY & VAIDYA LLP 515 E. BRADDOCK RD SUITE B ALEXANDRIA, VA 22314			EXAMINER MITCHELL, LAURA MCGILLEM	
			ART UNIT 1636	PAPER NUMBER
			NOTIFICATION DATE 01/15/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,902	Applicant(s) SCHULE ET AL.	
	Examiner Laura M. Mitchell	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a method for identifying a compound that promotes the activity of osteoblasts and preparing a compound that is useful in treating bone disease.

Group II, claim(s) 7-8, drawn to a compound that is useful in the treatment of bone disease.

Group III, claim(s) 9-14, drawn to a method for treatment of bone disease comprising administering a medicament comprises an Fhl2 nucleic acid.

Group IV, claim(s) 15-16, drawn to a method of diagnosing a bone disease.

Group V, claim(s) 17-19, drawn to a method for developing a medicament useful for treating bone diseases and promotes the activity of osteoblasts.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Groups lack a special technical feature and lack unity because the compound that is capable of promoting osteoblast activity was known in the prior art (see Amaar et al, 2002, Insulin-like Growth Factor-binding Protein 5 (IGFBP-5) Interacts with a Four and a Half LIM Protein 2 (FHL2) Vol. 277, No. 14 Pages 12053-12060). Amaar et al teach that IGFBP-5 interacts with Fhl2, and specifically found that FHL2/IGFBP-5 can co-immunoprecipitate in whole cell lysate from human

osteosarcoma cells (see page 12059, left column 2nd paragraph). Amaal et al suggest that IGFBP-5 may bind to FHL2 to stimulate transcription of putative IGFBP-5 target genes that may be involved in regulation of osteoblast cell proliferation and differentiation (see page 12059, for example), which meets the limitation of a compound capable of promoting translocation of Fhl2 protein into the nucleus.

The compound of Group II is materially distinct from the methods of Groups I and III-V. The use of the compound of Group II is not restricted to any one Group because it can be used in multiple methods. For example, the compound of Groups II can be used in a method for the development of a medicament for bone disease using a transgenic animal or it could be used in an *in vitro* screening method.

The technical feature of Group I is the step of determining *in vitro* if a test compound can modulate the activity of Fhl2, which is not found in the methods of the other Groups and distinguishes it from Groups III-V. The outcome of the method of Group I is an identified and synthesized compound that promotes activity of osteoblasts, which is distinguished from the outcomes of the methods of the other Groups.

The technical feature of Group III is a step of administering a medicament comprising an Fhl2 nucleic acid to a patient, which is not found in the methods of the other Groups and distinguishes it from Groups I and IV-V. The outcome of the method of Group III is a patient that has been treated for a bone disease with an Fhl2 nucleic acid, which is distinct from the outcomes of the methods of the other Groups.

The technical feature of Group IV is a step of determining the expression level of the Fhl2 gene in tissue from an individual and making a diagnosis of bone disease

based on a comparison of the expression level to a control level, which is not found in the methods of the other Groups and distinguishes it from Groups I, III and V. The outcome of the method of Group IV is a patient that has been diagnosed with a bone disease based on the level of Fhl2 gene expression in sample tissue, which is distinct from the outcomes of the methods of the other Groups.

The technical feature of Group V is a step of determining the effect of a test compound on the level of Fhl2 in a transgenic animal by examining the effect of the compound on osteoblast activity in the animal, which is not found in the methods of the other Groups and distinguishes it from Groups I and III-IV. The outcome of the method of Group V is a developed medicament for bone disease based on its ability to alter the activity of osteoblasts in a transgenic model animal, which is distinct from the outcomes of the methods of the other Groups.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

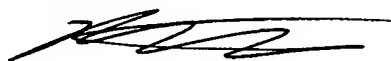
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell
Examiner
1/3/2008

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over a horizontal line.